Summary of Safety and Effectiveness As Required by 807.92(c) for the Distal Volar Radius Fracture Repair System

DEC - 5 2000

Submitted by

Hand Innovations, Inc.
8905 SW 87th Avenue
Suite 100
Miami, FL 33176-2227
Phone: (305) 661-3054
Fax: (305) 595-6620

Contact Person: Al Weisenborn

Device Trade Name: Distal Volar Radius Fracture Repair System
Common Name: Distal Volar Radius Locking Plate with pegs and screws
Classification Name: Single/multiple Component Metallic Bone Fixation Appliances and Accessories, per § 888.3030

Identification of a Legally Marketed Predicate Device

The Hand Innovations, Inc. Distal Volar Radius Fracture Repair System (DVR) is substantially equivalent to the Distal Radius Plate System that is manufactured by manufactured and distributed by Synthes (USA) pursuant to K982732.

Device Description

The DVR system consists of a stabilization plate, four bone screws, and four fixation pegs. The screws are used to fix the proximal segment of the plate to the diaphysis and the pegs the distal bone fragment(s). The required components and specialized instruments are supplied non-sterile in a container suitable for steam sterilization. All components and instruments may be purchased separately.

Intended Use

The Distal Volar Radius Fracture Repair System is intended for the volar fixation of fractures and osteotomies involving the distal radius.

Summary of Technological Characteristics

The DVR is substantially equivalent to equivalent to the Distal Volar Radius Fracture Repair System that is manufactured by manufactured and distributed by Synthes (USA) pursuant to K982732. This has been demonstrated through a 15 point comparison of technological characteristics.

Summary of Performance Data

A dimensional analysis of the DVR fracture repair system components met design requirement. Tensile strength performance characteristics of the DVR and predicate device were tested; the DRV was found to meet or exceed the measured performance characteristics of the predicate device.

Conclusion

The DVR has been demonstrated to be equivalent to the Distal Radius Plate System that is by manufactured and distributed by Synthes (USA) pursuant to K982732, Inc. by bench testing of both devices and comparison of technological characteristics.

The tissue/bone contact material of the device have been carefully selected for its long history of biocompatibility. The material meets the requirements of a recognized consensus standard for implantable orthopedic material.

The DVR was designed utilizing design controls compliant with the Quality System Regulation. The DVR will be manufactured per specifications and good manufacturing practices that ensure the device is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 5 2000

Hand Innovations, Inc.
c/o Mr. Al Weisenborn
Regulatory Affairs Specialist
19526 East Lake Drive
Miami, Florida 33015

Re: K002775
Trade Name: Distal Volar Radius Fracture Repair System
Regulatory Class: II
Product Code: 87, HRS
Dated: September 5, 2000
Received: September 6, 2000

Dear Mr. Weisenborn;

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Milhorn

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Page 1 of 1

510(k) Number (if known): K002775

Device Name: Distal Volar Radius Fracture Repair System

Indications for Use:

The Distal Volar Radius Fracture Repair System is intended for the volar fixation of fractures and osteotomies involving the distal radius.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N. Milhous

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K002775

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)